

**REMARKS**

The present invention is directed to methods and compositions for the oral vaccination of healthy animals through drinking water or syrups as an aid in the prevention of disease.

The Examiner has placed a restriction requirement upon the Application under 35 USC § 121 to one of the following Examiner defined groups: Invention II, Claims 1-10 drawn to a method of providing protection against disease in an animal by administering an oral vaccine; and Invention I, Claims 21-26 drawn to an animal vaccine comprising bacterium and virus, and Invention III, Claims 11-20 drawn to methods of inducing increased intake of an oral vaccine.

Applicants confirm the election of Invention II, as defined by the Examiner, and continue prosecution of Claims 1-10, with “bacterium” as the elected species. Applicants reserve the right to file a divisional Application directed to the non-elected subject matter.

The Abstract of the disclosure was objected to because the number of words contained in the Abstract exceeded the 150 words, as allowed by MPEP § 608.01 (b). The Abstract has been amended to decrease the number of words contained therein to 150 or less.

Claim 1 has been amended to recite in part, “admixing a water soluble palatable flavorant selected from the group consisting of fruit, fish and meat flavorants.” The Detailed Description of the Invention at page 5 lines 11-15 lists non-limiting examples of flavorants that include fruit, fish and meat flavors. Thus, the Detailed Description enables the amendment to claim 1.

New claims 27-30 are directed to additional preferred embodiments of the invention. Their support is taken from the specification at page 5, lines 11-15, for example.

**35 U.S.C. § 112 Objections**

The Examiner has objected to informalities in the Specification. Specifically, the Office objected to the lack of a “Priority” section in the first paragraph of the specification. The Specification was further objected to for typographical errors on pages 27 and 28 and for a misspelling on page 31. Accordingly, the specification has been amended by the forgoing amendments to address the informality rejections. Withdrawal of this objection is respectfully requested.

35 U.S.C. § 112 Rejections

The Office has rejected Claims 1-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, Claims 1, 2, 3 and 10 have been rejected for indefiniteness, spelling, lacking of the proper preceding article and failing to properly recite the Markush format. Claims 2-10 have been further rejected because the claims depended directly or indirectly from Claim 1, which was rejected as noted above for indefiniteness.

Claims 1, 2, 3 and 10 have been amended in a sincere attempt to address the Office's concerns and to better define the invention. Withdrawal of these rejections is respectfully requested.

35 U.S.C. § 102 Rejections

Claims 1-3, 5, 6 and 9 have been rejected under 35 U.S.C. § 102(e) as being anticipated by the prior art. Applicants respectfully traverse this rejection.

Claim 1 has been rejected under 35 U.S.C. § 102(e) as being anticipated by Heo *et al.* (US 6,491,956) as evidenced by Bakal *et al* (US 4,414,229). Heo *et al.* '956, discloses a food for human consumption that contains an active strain of a non-toxic living microorganism, that microorganism being either *Lactobacillus acidophilus* HY2177 or *Lactobacillus casei* HY2743. The food containing the microorganism is delivered by liquid yogurt, butter, milk, cream cheese or ice cream, in a nutritional yogurt drink. The *Lactobacillus* is introduced into the stomach for the purpose of colonizing in the stomach, thus inhibiting the attachment of *Helicobacter pyloti* (hereafter *H. pylori*) to gastric mucosal cells, to inhibit the production of urease and to inhibit the production of *Interleukin -8*. Bakal *et al.* '229, teaches that a butter-flavored, water-soluble, flavorant may be distilled and reconstituted from skim milk.

It should be noted that the Heo *et al.* '956 reference does not disclose a water-soluble fruit, fish or meat flavorant, as set forth in amended Claim 1 and in the Application's specification. Additionally, the Heo *et al.* '956 method is limited to human consumption, whereas the instant application is directed to providing protection against disease in an animal. Therefore, Heo *et al.* '956 and the instant invention relate to different approaches to treating disease. In light of the above differences, Heo et al. '956 as evidenced by Bakal *et al.* '229, does not anticipate the instant invention. Applicants therefore respectfully traverse

the 35 U.S.C. § 102(e) anticipation rejection. Withdrawal of the 35 U.S.C. § 102(e) anticipation rejection is respectfully requested.

Claims 1-3, 5 and 6 were rejected under 35 U.S.C. § 102(e) as being anticipated by Casas *et al.* (US 6,100,388) as evidenced by Bakal *et al.* '229. Casas *et al.* '388 describes a Lactobacilli vaccine that can be delivered by use of a pharmaceutically acceptable carrier or it can be added to milk or milk products such as yogurt. As noted above, Bakal *et al.* '229, teaches that a butter flavored, water soluble flavorant may be distilled and reconstituted from skim milk.

The Casas *et al.* '388 reference does not disclose the use of a water-soluble fruit, fish or meat flavorant, as set forth in amended Claim 1 and in the Application's specification. Therefore the Casas *et al.* '388 reference, as evidenced by Bakal *et al.* '229, does not anticipate the instant invention. Applicants respectfully traverse the 35 U.S.C. § 102(e) anticipation rejection. Withdrawal of the 35 U.S.C. § 102(e) anticipation rejection is respectfully requested.

Claims 1-3, 5, 6 and 9 were rejected under 35 U.S.C. § 102(e) as being anticipated by Clements *et al.* (US 6,019,982) as evidenced by Bakal *et al.* '229. The Clements *et al.* '982 patent at Section 5.2, column 14, line 39 states that the vaccine "may be reconstituted as a suspension in buffered saline, milk, or any other physiologically compatible liquid medium." The reference goes on to state that coloring and flavoring agents may be added as desired.

The Clements *et al.* '982 reference does not disclose the use of a water-soluble fruit, fish or meat flavorant, as specified in amended Claim 1 and in the Application's specification. Therefore, the Clements *et al.* '982 reference as evidenced by Bakal *et al.* does not anticipate the instant invention. Applicants respectfully traverse the 35 U.S.C. § 102(e) anticipation rejection. Withdrawal of the 35 U.S.C. § 102(e) anticipation rejection is respectfully requested.

### 35 U.S.C. § 103 Rejections

Claims 1, 4, 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Casas *et al.* '388 or Clements *et al.* '982 in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32). Grieve discloses using drinking water as an administrating vehicle for delivering vaccines to poultry. As noted above Casas *et al.* '388 and Clements *et al.* '982 disclose vaccination methods and materials. The Office has stated that it would have been

obvious to extend the teaching of the Grieve reference to the methods and compounds described in Casas *et al.* '388 and Clements *et al.* '982.

The Casas *et al.* '388 and Clements *et al.* '982 references do not disclose the use of a water-soluble fruit, fish or meat flavorant, as set forth in amended Claim 1 and in the Application's specification. Similarly, while the Grieve reference discloses using drinking water with a blue stain as an administering vehicle for vaccines in poultry, it does not disclose or render obvious the use of water soluble flavorants in an orally administered poultry vaccine. Therefore, the instant invention would not be rendered obvious in view of the Casas *et al.* '388 and Clements *et al.* '982 references when combined with the Grieve reference. Applicants respectfully traverse the 35 U.S.C. § 103(a) obviousness rejection. Withdrawal of the 35 U.S.C. § 103(a) obviousness rejection is respectfully requested.

Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Casas *et al.* '388 or Clements *et al.* '982 as modified by Grieve and further in view of Roland (US 6,399,074). Roland '074 discloses using a syringe for oral administration or vaccination to birds. As noted above, the Grieve article discloses using drinking water as an administrating vehicle for delivering vaccines to poultry and Casas *et al.* '388 and Clements *et al.* '982 disclose vaccination methods and materials. The Office has stated that it would have been obvious to extend the teaching of the Grieve article to the methods and compounds described in Casas *et al.* '388 and Clements *et al.* '982, and to further extend the method of using a syringe for oral administration or vaccination to birds as provided in Roland '074 reference.

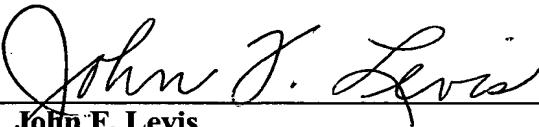
Without addressing the merits of the multiple extensions of references, the instant invention is patentable in light of the cited art because the references do not teach or render obvious the use of use of a water-soluble fruit, fish or meat flavorant, as set forth in Claim 1 and in the Specification. Therefore, the instant invention is not obvious in view of the Casas *et al.* '388 or Clements *et al.* '982 references when combined with the Grieve and Roland '074 references. Applicants respectfully traverse the 35 U.S.C. § 103(a) obviousness rejection. Withdrawal of the 35 U.S.C. § 103(a) obviousness rejection is respectfully requested.

Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Clements *et al.* '982 as modified by Grieve and further in view of Frantz *et al.* (US 5,536,496). The Frantz *et al.* reference discloses a vaccine composition containing an alkaline-toxoided *Pasteurella multocida* protein necrotizing toxin capable of inducing production of an amount

of antitoxin effective to neutralize the toxin in a carrier suitable for internal administration. The Casas *et al.* '388 and Clements *et al.* '982 references disclose vaccination methods and materials

As noted above, neither Clements *et al.* '982 nor Grieve disclose the use of a water soluble fruit, fish or meat flavorant, as does the instant invention. The Frantz et al. reference makes no reference to the use of flavorants. Therefore, the instant invention is not obvious in view of the Clements *et al.* '982 as modified by Grieve and in further view of Frantz et al. reference. Applicants respectfully traverse the 35 U.S.C. § 103(a) obviousness rejection. Withdrawal of the 35 U.S.C. § 103(a) obviousness rejection is respectfully requested.

Applicants believe that the present application is in condition for allowance and respectfully request that the Office enter the amendments, reconsider the rejections in light of the remarks herein and allow the application. Favorable treatment of the application is earnestly solicited. Should Examiner Devi feel that any other point requires consideration, then she is cordially invited to contact the undersigned.



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